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Trial Affidavit of Raymond Pironti

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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
THIS DOCUMENT RELATES TO: ALL CLASS ACTIONS	CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris

DECLARATION OF G. RAYMOND PIRONTI, JR.

1. My name is G. Raymond Pironti, Jr. I reside at 19010 Cour Estates, Lutz, Florida.

2. I am currently self-employed as a Partner/Owner in the following Florida companies: DSRP Consulting, LLC; JJ Ellis, LLC; and Mainsail Business Solutions, LLC. A brief description of these companies is included in the attached resume that outlines my background qualifications, professional experience, education and achievements.

3. I was an employee of the Schering-Plough Corporation (SP) from October 1990 through December 1998. Prior to working for SP, I obtained a Bachelor of Science in Finance and Marketing (Dual Major) from Syracuse University, School of Management, in 1990.

4. The facts set forth in this declaration are based upon my personal knowledge acquired in the regular course of business in my employment with SP in the positions I was assigned over the course of eight years. The positions of analyst or manager, time periods held, and a brief description of the duties and responsibilities of the positions I held at SP are described on page two of my attached resume. Generally, my experience allowed me to obtain

extensive and detailed knowledge as to the marketing, contracting, managerial, data systems, and financial operations of SP in the managed care and disease management business units.

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5. During the course of my employment with SP, I, along with two other SP employees (Beatrice Manning and Charles Alcorn), identified certain fraudulent practices involving SP's reporting of inflated "best prices" for SP drugs for the calculation of Medicaid rebates. In 1998 I met with Jim Sheehan from the Eastern District of Pennsylvania US Attorneys Office, and eventually filed a sealed complaint as a co-plaintiff with the US government under the qui tam provisions. I cooperated with the U.S. Attorney's Office investigation of SP's illegal marketing practices, including supplying copies of SP documents. Some of the previously supplied documents to the DOJ have now been produced in this case under Judge Saris' December 13, 2002 Protective Order, an order that I have signed onto by executing Exhibit A prior to seeing any documents produced by SP in this case. The qui tam action resulted in a global resolution during the summer of 2004 with the United States Attorney for the Eastern District of Pennsylvania that included the following components: (1) SP's wholly-owned subsidiary, Schering Sales Corp., pled guilty to a violation of the Anti-Kickback Statute for paying a kickback to two customers in exchange for preferred formulary treatment of Claritin and SP paid the fine of $52.5 million assessed for the criminal violation; (2) SP agreed to settle its False Claims Act liability and to pay to the United States, 50 Medicaid programs, and certain Public Health Service entities $292,969,482 for Schering's failure to report its true best price for Claritin; and (3) SP entered into a Corporate Integrity Agreement with DHHS to correct its government pricing reporting failures.

OBJECTION

Fed. R. Evid. 402, 403
See Memorandum, Part I

Fed. R. Evid. 404(b)
See Memorandum, Part II

6. The underlying facts supporting the qui tam action were that SP had used an intricate scheme that involved its subsidiaries, including ITG, Schering Corporation and Warrick Pharmaceuticals, to cheat Medicaid out of hundreds of millions of dollars. SP evaded its responsibility to charge the U.S. government and its beneficiaries the lowest price it charged to the private sector, i.e., the best price required by federal law. Most of the scheme was carried out through ITG. The scheme, which centered on SP's blockbuster drug Claritin, involved "kick-backs", hidden rebates, hidden discounts, unreported free goods and nominally priced drugs .

OBJECTION

Fed. R. Evid. 402, 403
See Memorandum, Part I

Fed. R. Evid. 404(b)
See Memorandum, Part II

7. ITG provided free or well-below-cost health management services to HMOs that put Claritin on formulary. The value of these services were not included in the best-price calculation SP used to establish Medicaid pricing. ITG would sign a contract with the HMOs and this contract would be ostensibly totally separate from the rebate contracts that SP would sign with the managed care organizations. Medicaid auditors would review the rebate contracts with SP (not ITG) and thus would never see the additional "kick-backs" or hidden rebates/discounts SP gave through ITG. The role of ITG services are reflected in Exhibit 565, a draft memo from Linda Zhou, who was then the head of SP's Contracts and Pricing division. In this memo, Zhou is making the "business case" for further investment into ITG's computer capacity. On page 2, under Roman numeral I, Zhou states, "ITG's services complement and enhance Schering's pharmaceutical products and meaningfully differentiate them from the competition. Thus, they provide our primary means of implementing the strategy to *compete on a basis other than price.*" On the next page under the section of "Increased Profitability" Zhou stated, "By allowing us to compete on a basis other than price, ITG has increased Schering Lab's profitability. Total discounts as a % of contracted gross sales has declined in 1996 from 23% in 1996 to 17% currently. At 1998 LE sales levels, this equates to annual savings of $222 million."

OBJECTION

Fed. R. Evid. 402, 403
See Memorandum, Part I

Fed. R. Evid. 404(b)
See Memorandum, Part II

In essence, the value of ITG services was a hidden discount to replace disclosed discounts on

certain SP drugs.

8. SP either directly or through a subsidiary also made money payments (kick-backs) or gave unreported free goods, including Warrick albuterol inhalers and solution, to major PBMs and HMOs when added value was required to overcome a competitive disadvantage against other pharmaceutical companies' deals. The money payments were disguised for reporting purposes as "administrative fees" "partnership fees" or "data fees." This occurred during the years shortly after OBRA'90 became effective and continued, at least, until I left SP in December 1998. I have personal knowledge of the use of such free goods because of the positions I held in the managed care and finance departments of Schering Labs and my positions in ITG. The use of free goods would not be reflected in best price calculations and subsequently posted AWPs. It was also a standard practice at SP that it would there would be no documentation i.e. contracts that linked transactions using free goods and customer discounts/pricing.

OBJECTION

Fed. R. Evid. 402, 403
See Memorandum, Part I

Fed. R. Evid. 404(b)
See Memorandum, Part II

9. SP also "gave" the managed care organizations (MCOs) nominally priced drugs, including SP Proventil and Warrick albuterol inhalers and solution, to equalize the difference between the "price" of an SP drug, such as Claritin, and the offered "price" of a competitor drug, such as Allegra, so that the SP drug would stay on a managed care organization's formulary. Nominal pricing of SP drugs was also used by SP to add value to deals with MCOs. "Nominal Prices" are steeply discounted drugs priced at 90% or more off of AMP. The value of nominally priced drugs to MCOs as a contract tool is premised on the fact that the MCO has a dispensing arm (pharmacy) and would sell the drug at full price or would be reimbursed as if acquired at

OBJECTION

Fed. R. Evid. 402, 403
See Memorandum, Part I

Fed. R. Evid. 404(b)
See Memorandum, Part II

regular direct price by third party payers using AWP-based reimbursement factors, such as

Medicare, plus any co-pays from the individual program beneficiary.

10. The nominal pricing strategy was first developed in October 1992 as shown by Exhibit 714. At that time I was a market analyst in managed care working under Ed Watson, an attendee to the nominal pricing meeting. Working in managed care, I was routinely briefed on contracting strategies and received a copy of Exhibit 714. The nominal pricing strategy was approved by senior management and thereafter implemented.

OBJECTION

Fed. R. Evid. 402, 403
See Memorandum, Part I

Fed. R. Evid. 404(b)
See Memorandum, Part II

11. Another strategy SP implemented to reduce medicaid liability, leverage managed care accounts and keep branded prices inflated was the Schering/Generic strategy set forth in Exhibits 609 and 408. Exhibit 609 is an early strategy paper on developing a generic arm of SP by Jim Audibert. Exhibit 408 is a follow-up white paper written by a team led by Rich Zahn. I am familiar with these two exhibits because I received file copies while working at SP. From these strategies, Warrick was created. Warrick, like ITG and the other SP subsidiaries are "shared resource" entities, i.e., they share SP's assets, resources and management in their operations. This latter concept of Warrick using SP resources is reflected in Exhibit 408 at WAR0006053 by the phrase "backroom" services.

OBJECTION

Fed. R. Evid. 402, 403
See Memorandum, Part I

Fed. R. Evid. 404(b)
See Memorandum, Part II

12. Nominal pricing, free goods, and generic drugs were tools utilized by SP to retain customers and formulary access without reducing the price or increasing the discount of selected high margin products such as Claritin. Typically SP would engage in the practice of "bundling" utilizing nominally priced product. The term "bundling" refers to grouping of different products regardless of class to achieve greater customer discounts and/or rebates. SP would analyze the customers historic drug utilization of all SP products. SP would then determine the impact of offering higher discounts or nominal prices for low margin mature multi-source heavily

OBJECTION

Fed. R. Evid. 402, 403
See Memorandum, Part I

Fed. R. Evid. 404(b)
See Memorandum, Part II

discounted products without discounting high margin single source products such as Claritin.

The offer would be presented as a package and rescinded if the customer did not accept the price for Claritin and maintain formulary position and utilization. Because the offer was implied and not directly linked, the products never appeared to be bundled. In some cases the MCO was considered a mixed model HMO (this type of customer has both a staff model HMO and an IPA model). SP would offer nominal pricing and/or free goods (if free goods there would be no contract pricing) with multi-source products to the staff model and in a separate contract to the IPA model secure formulary access with low discounts for the single source drug. There was no reference in either contracts to the bundle, thus appearing to be poor business practice (in the case of nominal pricing) but allowable under the law to a government auditor. Bundling affects AMP and best price calculations. HCFA required that the value of the discounted (nominally priced) or free product be proportionately distributed among the other products in the bundle. The nominal pricing strategy as shown in Exhibit 714 was implemented utilizing bundling, but, to my knowledge SP did not proportionately distribute the value of the nominally priced discount or report such bundling in accordance with HCFA requirements. An example of an implied bundling is Exhibit 470 where SP is structuring a deal with Medco whereby Warrick would make up any value difference from competition by providing Medco with $2.16 million by providing discounted/nominal solution. Another example of bundling is Exhibit 418. Exhibit 418 is actually a copy from a file I maintained at SP and the handwriting on the first page "separate Warrick bid" is mine. The managed care with GeriMed included SP branded versions of albuterol products. The "deal" was that GeriMed would receive discounted Warrick generic albuterol solution under a separate contract so as to hide the "discounted" drugs so as not to

report the discount for the branded versions. The practice of nominal pricing in contracting began in 1992 and continued, at least, up to the time I left SP in December 1998.

13. I have reviewed Exhibit 505 showing accounting of Intron-A and Proventil and Warrick solution as free goods for the years 1998 through 2003. Based on my experience in contracting at SP, there would not have been any reporting of those free goods to impact AMP, BP or AWP. Also based on my experience, the high volume entries at WAR 0072336 of free goods provided to Cardinal Health, a wholesaler, and Rite-Aid, a chain pharmacy, potentially indicate the giving of value in a bundling arrangement that would be structured so as to avoid reporting for best price. Likewise, such free goods would not be reflected in best price calculations.

OBJECTION

Fed. R. Evid. 402, 403
See Memorandum, Part I

Fed. R. Evid. 404(b)
See Memorandum, Part II

Fed. R. Evid. 602
See Memorandum, Part III

14. I have reviewed Exhibit 497, authored by Brian Longstreet. The comments in said exhibit regarding creating favorable reimbursements spreads through manipulations of AWP and sales pricing for both branded and generic products reflect a well-known strategy by SP senior management in the marketing of SP products.

OBJECTION

Fed. R. Evid. 602
See Memorandum, Part III

I declare under penalty of perjury that the foregoing is true and correct.

G. Raymond Pironti, Jr.

Dated: 10-27-06

G. Raymond Pironti, Jr.

19010 Cour Estates, Lutz, FL 33558 **e-mail: ray-pironti@tampabay.rr.com** **(813)404-2804**

Summary of Qualifications:

- A unique blend of business and information technology experience. Over thirteen years of experience in the pharmaceutical and healthcare industry focused on leveraging data and technology to deliver solutions to meet customer needs.
- High degree of interaction with major pharmaceutical companies and managed health care organizations including customer presentations with key decision-makers.
- Comprehensive knowledge of pharmaceutical managed care selling models, health management programs, and pharmacy programs with the ability to develop strategies, recommendations, analyses, selling tools, and contract designs to meet specific client/customer needs in a competitive and dynamic market environment.

Professional Experience:

2004 – Present **Self Employed - Partner/Owner in the following companies:**

DSRP Consulting, LLC – A Management Consulting, IT Consulting, and Analytics company Incorporated in Florida in 2004

JJ Ellis, LLC – A investment and real estate investment company incorporated in Florida in 2004

Mainsail Business Solutions, LLC – A Employee Healthcare Benefit Consulting company and licensed Insurance Agency incorporated in Florida in 2005

11/99 – 4/04 **Dendrite International, Inc. - Morristown, NJ**

Director, Pharmacy Operations, 1/02 – 4/04

- Responsible for the operations of Dendrite's data warehouse for Longitudinal Patient Data (LPD), the largest LPD data warehouse in the US, utilizing NCR's Teradata Warehouse platform. Responsibilities included the oversight and management of: all production processes, quality assurance, data mart design and production, client data hosting, environment capacity planning and stability, process change control, ISO 9000 compliant process mapping and documentation, development/implementation of new processes and applications, and the development and implementation of environmental/departmental performance metrics.
- Supervised production and operations staff; defined requirements, set priorities, and co-managed senior level development staff.
- Managed client and data supplier relationships; act as the primary technical and operational contact, including assisting sales team in proposal generation.
- Designed, negotiated, and managed service level agreements with internal and external customers.
- Provided both technical and business expertise and guidance to pharmacy consortium partners in the development and delivery of services such as compliance and persistence program measurement.
- Assisted senior management with the development of corporate strategy for Dendrite's LPD data and analytic services business.
- Continued to provide both client and internal team support in the form of business and technical expertise in the area of managed care and account based selling.

Director, Managed Care and Account-Based Selling, 11/99 - 12/01

- Product management responsibility for Dendrite's managed care and account-based selling sales force automation applications. Responsibilities included: developing the business case for applications/enhancements, managing the development of prototype applications, providing business expertise and intellectual property used in prototype development, development of marketing materials, proposal generation, sales support, and client presentations.
- Provided expertise and guidance to clients in adapting Dendrite's managed care and account-based solutions to meet specific needs and requirements of their organizations. This included definition of business rules, integration of legacy transaction systems, and evaluation and integration of third party data sources to deliver desired solutions.
- Product management responsibility for PharmaNet-Connect, a web portal designed specifically for pharmaceutical sales and marketing organizations. Responsibilities included: management of content

vendor relationships, business expertise and input in product design, development of marketing materials, proposal generation, sales support, and client presentations.

7/98 – 10/99 **Consultant**

EDS/MCI System House - New York, NY

- Provided expertise on the application and integration of web-based information management applications to pharmaceutical and healthcare industry customers.
- Assisted clients in understanding and applying information management solutions to meet their needs. This included advice and expertise on the integration of hardware, software, and data sources.
- Managed a team of specialists in the integration of web-based information management solutions for pharmaceutical clinical trial information.

Capitated Disease Management Services, Inc. - Montclair, NJ

- Provided expertise and oversight of disease management data services to clients.
- Advised pharmaceutical clients in the development of marketing and pricing strategies.
- Managed a team in the development of profitability and pricing models to assist pharmaceutical companies in contract development and negotiations.

10/90 – 12/98 **Schering-Plough Pharmaceuticals - Kenilworth, NJ**

Manager, Health Care Analytics, Integrated Therapeutics Group, 8/97- 12/98

- Primary responsibilities included: customer presentations to key decision makers, working with customers to design and implement health management programs, the design of applications for health management reporting, assisting ITG's internal medical staff in the development of disease algorithms that automate clinical interpretation of data, and vendor management.
- Developed enhancements to ITG's asthma disease algorithm, addressing sophisticated disease issues.
- Designed, developed, and implemented an application that compared summarized medical claim data, pharmacy claim data, and health risk assessment survey data to determine patient risk, care issues, and suggested intervention action plans for selected diseases.

Manager, Health Management Operations, Integrated Therapeutics Group, 11/95 - 8/97

- Primary operational support responsibilities included: data acquisition, data analysis, return on investment analysis, customer presentations, negotiation with key decision makers, contract design, implementation of programs, and presentation of program outcomes to customer senior management and key decision makers.
- Designed the asthma disease algorithm for identifying asthma patients and associated costs.
- Developed, designed, and implemented an application that utilized summarized patient pharmacy and medical claim data to identify patients with care issues for specific diseases.
- Developed and managed the implementation of a health management analysis for use with large employers. Presented this analysis to the senior management of a Fortune 10 company.

Manager, Disease Management Support, 10/94 - 10/95

- Played a key role in the design and development of health management programs for ITG in the areas of asthma, prostate cancer, hepatitis, and cardiovascular disease.
- Performed data analysis and provided recommendations for the development of contract structures.
- Additional responsibilities included field support, account presentations, and the development of reporting standards for disease management.

Managed Care Contract Manager, 4/94 - 10/94

- Primary responsibilities included: analysis of field proposals, market analysis to determine pricing and potential profitability, and contract design for GPOs, HMO's, PBMs, and nursing home providers.
- Provided extensive support in the development and installation of a third party pharmaceutical rebate and contract management system.

Managed Care Markets Analyst, 6/91- 3/94

- Designed, developed, and implemented a pharmaceutical rebate contract management system.
- Performed market analysis and assisted in the development of pricing strategies.

Marketing Research Analyst, 10/90 - 6/91

- Supported senior analysts and product managers by providing secondary data reports.
- Performed analytical studies and ad-hoc analyses as requested.

Education:

1990 **Syracuse University, School of Management – Syracuse, N.Y.**
Bachelor of Science, Finance and Marketing (Dual Major)

Achievements:

1996 ***Schering-Plough Excellence Award -*** For the design, development, and successful implementation of the CareMetric™ application

1994 ***Schering-Plough Excellence Award -*** For the design, development, and successful implementation of a rebate management system